

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Women's self-reported experiences using misoprostol obtained from drug sellers: a prospective cohort study in Lagos State, Nigeria
AUTHORS	Stillman, Melissa; Owolabi, Onikepe; Fatusi, Adesegun; Akinyemi, Akanni; Berry, Amanda; Erinfolami, Temitope; Olagunju, Olalekan; Väisänen, Heini; Bankole, Akinrinola

VERSION 1 – REVIEW

REVIEWER	Lisa Vallely Kirby Institute, UNSW, Australia
REVIEW RETURNED	10-Oct-2019

GENERAL COMMENTS	<p>Dear Authors</p> <p>I think this a well written and important piece of work, well done. I have a few small comments to make. Most importantly I am concerned that in the paper you do not clearly indicate how consent was obtained from the women, prior to the interviews being conducted by the research team. I can see a lot of information in the supplementary files about the process of how drug sellers were approached and recruited. I am wondering what consent the drug sellers got from the women before passing their information onto the study team for the follow-up interviews. From the way the paper is written it seems that verbal consent was obtained at time of phone interview. What about consent before the details were collected into the log/ register maintained by the drug sellers?? I think this needs explaining in the paper.</p> <p>Other small things:</p> <p>I am not sure that adding the DHS data in Table 1 adds anything to the paper. You mention it briefly in the discussion. I don't think it adds anything to the paper/ study and could be removed from the table and discussion section.</p> <p>P12, line 16: I think you should refer to "women", not Sample.</p> <p>P13, lines 13-13: A typo I think, I would write: "on average.....necessary for successful self-management of abortion using misoprostol."</p> <p>In the tables I don't think you need to include Lagos, 2018 in the headings.</p> <p>Good luck!</p>
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REVIEWER	Heidi Moseson Ibis Reproductive Health, USA
REVIEW RETURNED	11-Nov-2019

<p>GENERAL COMMENTS</p>	<p>Thank you for this important contribution. Prospective evaluation of self-managed abortion with misoprostol alone is much needed, and these findings provide important insight into the experiences of several hundred drug sellers, as well as individuals in Lagos. The data presented provide strong evidence that self-managed abortion with misoprostol is effective and safe, even when the information (or dosage) provided is incorrect. These data challenge some assumptions about self-managed abortion in a way that bolsters confidence in this model of care.</p> <p>Overall, the paper could benefit from consistency throughout in presenting N and % together for all outcomes, writing more gender-inclusively about the experience of unintended pregnancy and abortion (rather than defaulting to “women” in all instances), and providing more clarity/direct estimates on missing data. I have included minor comments below by section.</p> <ul style="list-style-type: none"> • Last bullet in strengths/limitations: Need to correct last phrase to be “...therefore our findings are not be generalizable to the entire population of the state and country.” <p>Introduction</p> <ul style="list-style-type: none"> • In recognition of the fact that people who identify with genders other than women can get pregnant and have abortions (i.e., transmen, non-binary people, etc), I would suggest using inclusive language where possible – not defaulting to “women” all the time, rather, discussing “people”, “individuals”, “participants”; or being specific “women, transgender men, non-binary people, and others capable of pregnancy”. If all participants explicitly identified as cisgender women state as much, otherwise, specify that participants were identified as “women” based on the assumptions of the pharmacy workers, or focus more on the specific eligibility that is relevant for the study: anyone who was attempting to end a pregnancy (woman or otherwise). Or, if authors insist on remaining with “women”, at the very least, I would encourage use of a footnote or parenthetical after the first use of women to acknowledge that people of many genders (genders other than women) can get pregnant and have abortions, but that for X reasons, you are using “women” throughout. • Just to raise a reflective question about the use of “sub-Saharan” as a regional descriptor – what is the significance of a country being located south of the Sahara? What meaningful sociodemographic or other characteristics fall along those lines? Some would argue it is more accurate/appropriate to describe regions in more specific terms: .e.g, West Africa, Southern Africa, East Africa, Central Africa, North Africa, etc • Some switching between past and present tense in discussion of the study, which is a bit distracting – would recommend revising to be consistent <p>Methods</p> <ul style="list-style-type: none"> • Selection of stratum: the authors specify that LGAs were selected with a higher-level education institution due to hypothesis that more female students – a group that authors hypothesize is more likely to have an unintended pregnancy. This is an empirical question. Can the authors provide a citation for this? One could argue that highly educated people, students or no, might be less likely to have unintended pregnancies due to knowledge/awareness/access to contraception. • GPS – spell out acronym first time used
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	<ul style="list-style-type: none"> • N and percent should be provided for all study results, not just one or the other or occasionally both – keep it consistent throughout • Informed consent – how did the authors handle the fact that some participants were given incorrect information about misoprostol use? Was there any intervention with drug sellers to insure that correct information on misoprostol use was given to people for pregnancy termination? In the informed consent, were participants directed to appropriate protocols for use? Or if data collector learned that a participant was told the incorrect protocol, was any corrected information given to that participant? As this is a central issue of this particular recruitment/follow-up design, it feels worthy of directly addressing in the main text. • It seems that gestational age was not measured in the study? If no, why not? And if yes, how was it measured and why are results not presented? • Need to mention planned comparison to Lagos DHS survey – otherwise it appears in Table 1 with no context or explanation – readers don't know how to interpret the data, where they came from, or why they are there and why the authors are comparing. So authors should be explicit about what these data are, how they are reporting on them, and to what end. <p>Results</p> <ul style="list-style-type: none"> • Abortion attempts prior to recruitment: results say 21 people tried something prior, and then methods are described for 22 people. Did some people try more than one method? (I presume?) • Table 2 should include a line for “missing” so that the reader can appreciate for how many people certain items were unknown – for instance, dosage of medication taken – it appears that findings are only reported for 251 of respondents (63% of participants) – if the rest are indeterminate, it is important to convey that – rather than leaving people to think that outcomes were X% percent with doses as listed in Table 2 – when really, you don't actually know the dosage for many participants. I.e., it feels imprecise to say “at least two-thirds didn't have full dose”, when – if you don't know dosage for 37% of your sample, could be way off • Table 4: methods section should clarify better the authors' distinction/definition of “clinical symptoms” vs “warning signs of complications” <p>Discussion</p> <ul style="list-style-type: none"> • The data on proportions followed-up at each stage should be in the results for study participants, not the discussion • For the comparisons made to Lagos DHS data, are these differences assessed with any formal statistical tests? Or are the authors simply reporting differences in point estimates, without evaluating overlap in confidence intervals/precision, etc? • The authors claim a “woman-centered approach” – can they elaborate as to how they view this approach as women centered? What specific aspects? Does this have implications for recommendations for other studies? • Given the involvement of a technical advisory board with much Nigeria-specific expertise, it would be a contribution if the authors could elaborate on the planned dissemination of findings in Nigeria, and if/how they may be used to change regulation/training/outreach to pharmacy providers (and/or other points of care for abortion) <p>Appendices:</p>
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	<ul style="list-style-type: none"> • The additional results presented in the appendices are an important contribution- it is great to see more detail and more context for many of the findings. • Details of follow-up listed in the Appendices indicate that interviewers called participants many times to reach them (i.e., “however, more than 20% of participants were called at least five times before interviewers successfully reached them for the screener and the first and second follow-up interviews with up to 16 attempted contacts required to successfully contact some respondents for interviews.”) Many studies will limit attempts to follow-up with participants to 3-4 attempts. Can the authors provide more information about participants’ sense of this intensity of follow-up? Did it feel burdensome? Or were participants’ appreciative of the attempts to include them? A mix of both? Conclusions/lessons learned from this approach for future studies?
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VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1

Reviewer Name: Lisa Vallely

Institution and Country: Kirby Institute, UNSW, Australia

Please state any competing interests or state ‘None declared’: None declared

Please leave your comments for the authors below:

Dear Authors I think this is a well written and important piece of work, well done.

1. I have a few small comments to make. Most importantly, I am concerned that in the paper you do not clearly indicate how consent was obtained from the women, prior to the interviews being conducted by the research team. I can see a lot of information in the supplementary files about the process of how drug sellers were approached and recruited. I am wondering what consent the drug sellers got from the women before passing their information onto the study team for the follow-up interviews. From the way the paper is written it seems that verbal consent was obtained at time of phone interview. What about consent before the details were collected into the log/ register maintained by the drug sellers?? I think it needs explaining in the paper.

Response: We added additional detail to the methods section and the appendix (main text page 6, appendix pages 4 & 5). We hope this clarifies that: when the drug sellers introduced the study to them, potential participants understood that by verbally agreeing to participate, the information provided would be recorded and shared with the study team. They also verbally agreed to be directly contacted by a member of the study team in the days after the purchase, and understood that the member of the study team would again explain the study and obtain verbal consent to participate. We utilized verbal consent throughout the study because in the pilot phase women clearly indicated that they did not feel comfortable appending their signatures to a paper consent form because of the study topic and our IRB agreed that verbal consent protected the participants’ confidentiality sufficiently. No personal information that could be used to identify someone was gathered by drug sellers.

Other small things:

2. I am not sure that adding the DHS data in Table 1 adds anything to the paper. You mention it briefly in the discussion. I don't think it adds anything to the paper/ study and could be removed from the table and discussion section.

Response: Thank you for bringing this up. We believe that it is important to include the comparison to the DHS data. Given that our sample was purposively selected, we cannot assume that it is representative of the general population of WRA in Lagos state. Therefore we think it is important to note the differences between our sample and that of the DHS (a survey designed to be representative) to be able to contextualize our findings. While we cannot compare our sample to a representative sample of women who had had an abortion in Lagos, we think that ever-pregnant women is the best available comparison group. We understand, though, that as originally drafted, the comparison to the DHS data in Table 1 needed a bit more explanation. We removed the DHS data from Table 1, and included them in a new table and added some text to Appendix C comparing the sociodemographic characteristics of our sample to that of the DHS (Appendix C Table 1, page 11).

3. P12, line 16: I think you should refer to "women", not Sample.

Response: The authors chose not to make this edit in an effort to remind the reader to keep our sampling methods in mind as we discuss the results.

4. P13, lines 13-13: A typo I think, I would write: "on average.....necessary for successful self-management of abortion using misoprostol."

Response: Corrected

5. In the tables I don't think you need to include Lagos, 2018 in the headings.

Response: Removed

Good luck !

Response: Thank you very much for your thoughtful comments.

Reviewer: 2

Reviewer Name: Heidi Moseson

Institution and Country: Ibis Reproductive Health, USA

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below:

Thank you for this important contribution. Prospective evaluation of self-managed abortion with misoprostol alone is much needed, and these findings provide important insight into the experiences of several hundred drug sellers, as well as individuals in Lagos. The data presented provide strong evidence that self-managed abortion with misoprostol is effective and safe, even when the information (or dosage) provided is incorrect. These data challenge some assumptions about self-managed abortion in a way that bolsters confidence in this model of care. Overall, the paper could benefit from consistency throughout in presenting N and % together for all outcomes, writing more gender-inclusively about the experience of unintended pregnancy and abortion (rather than defaulting to "women" in all instances), and providing more clarity/direct estimates on missing data. I have included minor comments below by section.

1. Last bullet in strengths/limitations: Need to correct last phrase to be "...therefore our findings are not be generalizable to the entire population of the state and country."

Response: Noted and corrected

Introduction

2. In recognition of the fact that people who identify with genders other than women can get pregnant and have abortions (i.e., transmen, non-binary people, etc), I would suggest using inclusive language where possible – not defaulting to "women" all the time, rather, discussing "people", "individuals", "participants"; or being specific "women, transgender men, non-binary people, and others capable of pregnancy". If all participants explicitly identified as cisgender women state as much, otherwise, specify that participants were identified as "women" based on the assumptions of the pharmacy workers, or focus more on the specific eligibility that is relevant for the study: anyone who was attempting to end a pregnancy (woman or otherwise). Or, if authors insist on remaining with "women", at the very least, I would encourage use of a footnote or parenthetical after the first use of women to acknowledge that people of many genders (genders other than women) can get pregnant and have abortions, but that for X reasons, you are using "women" throughout.

Response: We greatly appreciate this comment. We recognize that people who identify with all genders (not only cisgender women) can get pregnant and may need abortion services. We also agree that using gender-inclusive language whenever possible is important. In some places, we have replaced the word "woman" with "people", or "individual", especially when referring to people generally in the introduction. For the purpose of this study, our eligibility criteria included being a woman 15-49 years old who had purchased misoprostol to terminate a pregnancy and the word "woman" was used in the consent form as well as the interviews. Given cultural norms in the context of Nigeria, we did not discuss gender-identity – we did not include any questions in the surveys about it and we did not discuss the issue during trainings. Throughout the paper, we refer to participants primarily as women because of assumptions made by the drug sellers who recruited them based on how they presented themselves at the time of purchase. There was also no objection by any participant to the assumption made by referring to them as women during the course of the interviews. We have added a footnote on page 5 of the manuscript explaining this.

3. Just to raise a reflective question about the use of "sub-Saharan" as a regional descriptor – what is the significance of a country being located south of the Sahara? What meaningful sociodemographic or other characteristics fall along those lines? Some would argue it is more accurate/appropriate to describe regions in more specific terms: .e.g, West Africa, Southern Africa, East Africa, Central Africa, North Africa, etc

Response: We agree that there are distinctions between countries in SSA along sociodemographic characteristics, and that for many reproductive health issues indicators tend to align more at the sub-regional level, or are even-country-specific. However, SSA is generally used in the literature, and is a reference point everyone understands. Furthermore, because this is the first published study of its kind in all of Africa, not only West Africa, we do not want to limit our language to include just the sub-region that includes the country (Nigeria).

4. Some switching between past and present tense in discussion of the study, which is a bit distracting – would recommend revising to be consistent

Response: We have revised the language in the discussion for consistency. The discussion is now written in the past tense when referring to our study findings. We think, however, that the language in the conclusion should remain in the present tense.

Methods

5. Selection of strata: the authors specify that LGAs were selected with a higher-level education institution due to hypothesis that more female students – a group that authors hypothesize is more likely to have an unintended pregnancy. This is an empirical question. Can the authors provide a citation for this? One could argue that highly educated people, students or no, might be less likely to have unintended pregnancies due to knowledge/awareness/access to contraception.

Response: Noted. We checked the literature on abortion incidence by age and education in Nigeria. PMA 2020 data shows higher estimates of abortion incidence among women in their 20s and women with secondary education or higher in Nigeria. This sentence was corrected to reflect this additional information and a citation was added (page 5).

6. GPS – spell out acronym first time used

Response: The full name has been added (page 5).

7. N and percent should be provided for all study results, not just one or the other or occasionally both – keep it consistent throughout

Response: We added the n and % for all results, but it was very distracting and negatively affected the readability of the manuscript. Therefore, we include %s when presenting proportions of the entire sample, and we present n's if the number of women we are reporting on is very small or if the %'s are among a subsample, to avoid confusion. If the editor of the journal require n's and %'s to be presented for all study results, we are happy to make this change.

8. Informed consent – how did the authors handle the fact that some participants were given incorrect information about misoprostol use? Was there any intervention with drug sellers to insure that correct information on misoprostol use was given to people for pregnancy termination? In the informed consent, were participants directed to appropriate protocols for use? Or if data collector learned that a participant was told the incorrect protocol, was any corrected information given to that participant? As this is a central issue of this particular recruitment/follow-up design, it feels worthy of directly addressing in the main text.

Response: Thank you for this important question. The original intention of this study was to document women's typical experiences and not to directly intervene in their misoprostol use. Thus, the fieldworkers did not receive medical training as part of this study and were not directed to intervene if respondents were not given correct information on misoprostol use, as not all respondents could successfully identify the medication they were given. Any respondents with concerns or questions were directed to contact Marie Stopes Nigeria hotline and the accident and emergency unit of the Lagos State University Teaching Hospital. All study participants were given these resource contacts upon completion of the final interview.

This study sought to document women's experiences of self-management of misoprostol use, but the team was responsive to requests for additional information/assistance by 12 respondents and text from page 5 of the appendix describes this protocol:

“Interviewers were trained to not give advice about any potential complications or directly answer health-related questions at any point in the women's interviews. During the screener or first follow-up interview, women who asked for medical advice or who described symptoms that could indicate a serious problem were provided with the numbers for the Marie Stopes Nigeria hotline and the accident and emergency unit of the Lagos State University Teaching Hospital. All women in the study were given this contact information after completion of the second follow-up interview, in case they

had additional medical questions. Women given hotline information in the screener or first follow-up interview were asked if they had contacted the hotlines, during the first and second follow-up interviews, respectively, to account for any bias this potentially gained information may have introduced into the results. Twelve women requested further information that prompted interviewers to provide the hotline number - two at the time of the screener interview and eleven during the first follow up interview (one woman requested more information during both interviews). However, none of the study participants successfully utilized the hotline.”

We added some of this detail to the main text on page 7.

9. It seems that gestational age was not measured in the study? If no, why not? And if yes, how was it measured and why are results not presented?

Response: Gestational age could not be accurately determined in this study. Although we did ask participants about the date of their last menstrual period, a number of the answers provided did not make sense and we are not certain they are reliable. This was not surprising, as evidence suggests that self-reported LMP is an unreliable measure. On page 18, in the discussion, we say “We could not accurately assess their weeks of gestation.”

Some useful references on the challenges of self-reported LMP:

Lynch, C. D., & Zhang, J. (2007). The research implications of the selection of a gestational age estimation method. *Paediatric and perinatal epidemiology*, 21, 86-96.

Savitz, D. A., Terry Jr, J. W., Dole, N., Thorp Jr, J. M., Siega-Riz, A. M., & Herring, A. H. (2002). Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination. *American journal of obstetrics and gynecology*, 187(6), 1660-1666.

Price, J. T., Winston, J., Vwalika, B., Cole, S. R., Stoner, M. C., Lubeya, M. K., ... & Stringer, J. S. (2019). Quantifying bias between reported last menstrual period and ultrasonography estimates of gestational age in Lusaka, Zambia. *International Journal of Gynecology & Obstetrics*, 144(1), 9-15.

10. Need to mention planned comparison to Lagos DHS survey – otherwise it appears in Table 1 with no context or explanation – readers don’t know how to interpret the data, where they came from, or why they are there and why the authors are comparing. So authors should be explicit about what these data are, how they are reporting on them, and to what end.

Response: Based on this helpful comment, and reviewer 1’s comment on this, we have removed the DHS comparison from Table 1. Given that our sample was purposively selected, we cannot assume that it is representative of the general population of WRA in Lagos state. Therefore we think it is important to note the differences between our sample and that of the DHS (a survey designed to be representative) to be able to contextualize our findings. While we cannot compare our sample to a representative sample of women who had had an abortion in Lagos, we think that ever-pregnant women is the best available comparison group. We understand, though, that as originally drafted, the comparison to the DHS data in Table 1 needed more explanation. We included the information in a new table and added some text to Appendix C comparing the sociodemographic characteristics of our sample to that of the DHS (Appendix C Table 1, page 11).

Results

11. Abortion attempts prior to recruitment: results say 21 people tried something prior, and then methods are described for 22 people. Did some people try more than one method? (I presume?)

Response: Yes, more than one method was attempted by a respondent. The sentence on page 10 reads: "...at least one other attempt to terminate the current pregnancy..."

12. Table 2 should include a line for "missing" so that the reader can appreciate for how many people certain items were unknown – for instance, dosage of medication taken – it appears that findings are only reported for 251 of respondents (63% of participants) – if the rest are indeterminate, it is important to convey that – rather than leaving people to think that outcomes were X% percent with doses as listed in Table 2 – when really, you don't actually know the dosage for many participants. I.e., it feels imprecise to say "at least two-thirds didn't have full dose", when – if you don't know dosage for 37% of your sample, could be way off

Response: We had attempted to add some caveats in the text, and had included footnotes and N's in Table 2 explaining that dosage and route of administration could only be assessed for a subsample, but we agree that as originally drafted, these results were a bit misleading. These two indicators in table 2 now represent the entire sample and include a row for "not assessed". In the results we present the % receiving less than the recommended dosage of 800 mcg misoprostol, including the non-assessed individuals in the denominator, which lowered the percentage. Additionally, in the discussion, we report our best estimate for the % receiving less than recommended dose and the % told a suboptimal administration route among those we were able to assess.

13. Table 4: methods section should clarify better the authors' distinction/definition of "clinical symptoms" vs "warning signs of complications"

Response: We removed the column for clinical symptoms in Table 4. The symptoms that could indicate potential complications were the data of interest in this table, and the only data from the table that are discussed in the text. We had already included the experience of expected clinical symptoms in a table in the appendix (Appendix C, Table 3). Main text Table 4 (page 14&15) now has extensive notes about the potential complications classifications, and these definitions are also included in Appendix B.

Discussion

14. The data on proportions followed-up at each stage should be in the results for study participants, not the discussion

Response: The authors moved this information to the beginning of the results section.

15. For the comparisons made to Lagos DHS data, are these differences assessed with any formal statistical tests? Or are the authors simply reporting differences in point estimates, without evaluating overlap in confidence intervals/precision, etc?

Response: The differences were not assessed with any formal statistical tests because our sample was not random and hence confidence intervals do not convey the same type of information they do in the DHS sample.

16. The authors claim a "woman-centered approach" – can they elaborate as to how they view this approach as women centered? What specific aspects? Does this have implications for recommendations for other studies?

Response: Thank you for this comment. We have revised the language on page 19 to say:

“These limitations were, in part, balanced by the strengths of the study, including its prospective design and its focus on women’s direct experiences rather than relying on third party reporting. However, our overall reliance on self-reported measures for many of our core outcomes makes it difficult to determine the extent to which our findings will correlate with clinical data and must be interpreted with caution.”

By woman-centered, we had intended to mean that our study centered our sample by recognizing them as the owners of their own unique needs and experiences and presenting their reports of such experiences. We do think other researchers could benefit from focusing on the direct reports of the people who are experiencing the issues of interest, while recognizing the limitations of such a study design, especially when attempting to assess clinical outcomes (explained in the discussion).

17. Given the involvement of a technical advisory board with much Nigeria-specific expertise, it would be a contribution if the authors could elaborate on the planned dissemination of findings in Nigeria, and if/how they may be used to change regulation/training/outreach to pharmacy providers (and/or other points of care for abortion)

Response: The involvement of the technical advisory committee, including its role in the development of the study and dissemination activities, is mentioned in the section on patients and public involvement on page 7. While we do know that we will present findings to drug sellers, the actual dissemination activities are not yet planned, so we are unable to elaborate on this at this stage. We are currently in the process of finalizing an in-country communications partner with whom we will collaborate closely to plan the dissemination and message the findings in the most policy-relevant and impactful way possible.

Appendices:

The additional results presented in the appendices are an important contribution- it is great to see more detail and more context for many of the findings.

18. Details of follow-up listed in the Appendices indicate that interviewers called participants many times to reach them (i.e., “however, more than 20% of participants were called at least five times before interviewers successfully reached them for the screener and the first and second follow-up interviews with up to 16 attempted contacts required to successfully contact some respondents for interviews.”) Many studies will limit attempts to follow-up with participants to 3-4 attempts. Can the authors provide more information about participants’ sense of this intensity of follow-up? Did it feel burdensome? Or were participants’ appreciative of the attempts to include them? A mix of both? Conclusions/lessons learned from this approach for future studies?

Response: We agree that limiting the number of attempts to three or four is common, especially for face-to-face interviews. Because this study used telephone interviews, logistically it was not an additional burden on the interviewers to continue trying to call participants over the course of the recruitment period. Getting a participant on the phone generally is subject to several issues ranging from personal to technical. Our reasoning for the multiple attempts is addressed on page 5 of the appendix (specifically phones being turned off). We cannot provide additional information about participant’s perception of our follow-up attempts because we did not explicitly ask them related questions, but according to the fieldworkers’ reports, most participants were unaware of the many attempts because their phones were not on. The research and field teams recommend this approach for similar studies.

VERSION 2 – REVIEW

REVIEWER	Heidi Moseson Ibis Reproductive Health, USA
REVIEW RETURNED	08-Jan-2020

GENERAL COMMENTS	<p>It is great to see the revisions the authors have made to this important work. I offer a few final comments in response to the author queries, and recommend that this manuscript is accepted for publication:</p> <ul style="list-style-type: none"> • I see that the results related to women who experienced expected clinical symptoms (headaches, nausea, vomiting, diarrhea) were moved to the Appendix. I found these data informative, and to provide helpful information for people to understand what can be expected as a normal part of self-managed medication abortion – so I am glad they were not deleted entirely! • I appreciate the authors' clarification regarding their uncertainty about the quality of self-reported gestational age data in their study. Depending on the scale of data quality issues with your gestational age data, I could understand the decision to not report it. If it was only a few data points that seemed implausible, perhaps it is worth reporting the data and then commenting on that? Or if it is more problematic than that, perhaps not. However, I would not say that implies that self-reported gestational age data in general are unreliable for assessment of medication abortion eligibility. While there is certainly evidence that self-reported gestational age based on LMP is not as precise as ultrasound dating one the scale of exact weeks of gestation, there is a reasonable amount of evidence suggesting that self-reported gestational age is comparably accurate to ultrasound dating in terms of assessing eligibility for medication abortion (e.g., Blanchard et al., 2007; Bracken et al., 2011; Constant, Harries, Moodley, & Myer, 2017; Schonberg, Wang, Bennet, Gold, & Jackson, 2014). • Regarding the comparison to DHS data, I appreciate the authors' inclusion of additional explanation for the comparison – it provides interesting context. If space is an issue, I still feel that the table could be removed because the comparison is not that informative. We do not know what proportion of ever-pregnant people in Nigeria choose to go to a pharmacy to end a pregnancy – there could be and likely are many reasons why we would expect a sample of not just abortion seekers but abortion self-managers, to differ from a sample of the broader group of ever-pregnant women, even aside from sampling method or representativeness. I suppose it is not harmful to leave it in, but just to be sure that you appropriately and clearly state that your study sample is a much narrower sample than we would expect from a sample of ever-pregnant women, and clarify that this is not meant to show what a representative sample of people who abort with medications purchased from a pharmacy would look like. • If at all helpful, we recently published a review of self-managed abortion in the literature, including discussion and listing of published studies on self-managed medication abortion effectiveness and safety – this could be a useful resource to feel certain that you have cited the relevant primary studies on effectiveness of self-managed medication abortion in discussion of your own findings (Moseson et al - Self-managed abortion: A
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	systematic scoping review – Best Practice & Research Clinical Obstetrics and Gynecology - https://doi.org/10.1016/j.bpobgyn.2019.08.002)
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VERSION 2 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 2

Reviewer Name: Heidi Moseson

Institution and Country: Ibis Reproductive Health, USA Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below It is great to see the revisions the authors have made to this important work. I offer a few final comments in response to the author queries, and recommend that this manuscript is accepted for publication:

- I see that the results related to women who experienced expected clinical symptoms (headaches, nausea, vomiting, diarrhea) were moved to the Appendix. I found these data informative, and to provide helpful information for people to understand what can be expected as a normal part of self-managed medication abortion – so I am glad they were not deleted entirely!

- I appreciate the authors' clarification regarding their uncertainty about the quality of self-reported gestational age data in their study. Depending on the scale of data quality issues with your gestational age data, I could understand the decision to not report it. If it was only a few data points that seemed implausible, perhaps it is worth reporting the data and then commenting on that? Or if it is more problematic than that, perhaps not. However, I would not say that implies that self-reported gestational age data in general are unreliable for assessment of medication abortion eligibility. While there is certainly evidence that self-reported gestational age based on LMP is not as precise as ultrasound dating on the scale of exact weeks of gestation, there is a reasonable amount of evidence suggesting that self-reported gestational age is comparably accurate to ultrasound dating in terms of assessing eligibility for medication abortion (e.g., Blanchard et al., 2007; Bracken et al., 2011; Constant, Harries, Moodley, & Myer, 2017; Schonberg, Wang, Bennet, Gold, & Jackson, 2014).

RESPONSE: While we did attempt to capture gestational age, and were hopeful that self-reported LMP data would allow us to present this useful measure, unfortunately, the reporting from our study on this measure was too problematic to include.

- Regarding the comparison to DHS data, I appreciate the authors' inclusion of additional explanation for the comparison – it provides interesting context. If space is an issue, I still feel that the table could be removed because the comparison is not that informative. We do not know what proportion of ever-pregnant people in Nigeria choose to go to a pharmacy to end a pregnancy – there could be and likely are many reasons why we would expect a sample of not just abortion seekers but abortion self-managers, to differ from a sample of the broader group of ever-pregnant women, even aside from sampling method or representativeness. I suppose it is not harmful to leave it in, but just to be sure that you appropriately and clearly state that your study sample is a much narrower sample than we would expect from a sample of ever-pregnant women, and clarify that this is not meant to show what a representative sample of people who abort with medications purchased from a pharmacy would look like.

RESPONSE: We agree and, given the limitations listed above, we have removed this table. We do state clearly that our sample was purposive and does not represent all people or all people using medication abortion in Lagos State, but think that the utility of including the table for context does not outweigh the potential confusion introduced by directly comparing of our sample with ever-pregnant women in the state.

- If at all helpful, we recently published a review of self-managed abortion in the literature, including discussion and listing of published studies on self-managed medication abortion effectiveness and safety – this could be a useful resource to feel certain that you have cited the relevant primary studies on effectiveness of self-managed medication abortion in discussion of your own findings (Moseson et al - Self-managed abortion: A systematic scoping review – Best Practice & Research Clinical Obstetrics and Gynecology - https://urldefense.proofpoint.com/v2/url?u=https-3A__doi.org_10.1016_j.bpobgyn.2019.08.002&d=DwIFaQ&c=euGZstcaTDIlvimEN8b7jXrwqOf-v5A_CdpqnVfiiMM&r=KCgdLPVC2Slc_Zizg6XyJzJ4a21K01d06cF5oF4aFOo&m=9wmHgg5wleMq7-t3-qDgWOpAwEDEU66DBWC-9yLmlew&s=mZMeosHVYKaGYkND2ieJZq28Sq4PR_wf2_wgGhgJo1s&e=))

RESPONSE: Thank you for this. We have included a couple more references in the discussion